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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,986 •	11/21/2001	Hideo Tashiro	05426/014001	1725
22511	7590	07/08/2004	EXAMINER	
OSHA & MAY L.L.P. 1221 MCKINNEY STREET HOUSTON, TX 77010			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,986

Applicant(s)

TASHIRO ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 22-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 22-24 is/are rejected.
7) ☒ Claim(s) 1 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 April 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 7 April 2004 in which claim 1 was, claims 2-21 were canceled and claims 22-24 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 7 January 2004, not reiterated below, are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1 and 22-24 are under prosecution.

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Specification

3. The amendment filed 7 April 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The specification at page 9 has been amended to replace the paragraph starting on line 3 with the following:

By the above steps (1) to (10), a DNA microarray support 100 which has avidin immobilized in a single layer to a layer of biotin ~~the DNA-immobilizing agent coating on~~ the specific areas (DNA-attachable spots) 101 on the surface of the slide glass 11 **is obtained**. The diameter of each spots is preferably equal to or smaller than 200 **mm**, and the space between the neighboring spots is preferably equal to or smaller than 400 **mm**.

The amended paragraph is improper because it does not accurately recite the original paragraph. The original paragraph follows:

By the above steps (1) to (10), a DNA microarray 100 which has avidin immobilized in a single layer **only to** the specific areas (DNA-attachable spots) 101 on the surface of the slide glass 11. The diameter of each spot is preferably equal to or smaller than 200 **µm**, and the space between the neighboring spots is preferably equal to or smaller than 400 **µm**.

The replacement paragraph amends numbers words and phrases that are not properly marked up as amended. Some of the misrepresented/omitted/inserted words and phrases are highlighted above. Because the paragraph is not consistent with the originally filed paragraph and specification, the amendment introduces new matter.

The amendments to the paragraphs on page 9 and 12 both introduce the phrase "layer of biotin". Applicant has not pointed to support for this newly added description and a review of the specification reveals no such support.

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Additionally, the Abstract has been amended to define the microarray as having a layer of biotin. Again, support is not pointed to and none is revealed. Hence, the phrase “layer of biotin” added to the specification and abstract introduce subject matter into the disclosure.

The Abstract has also been amended to insert “a uniform shape and size determined by photolithography”. While the specification teaches photolithography steps for making the microarray, the specification does not teach or describe determination of size and/or shape using photolithography. Applicant has not pointed to support for this newly added description and a review of the specification reveals no such support.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

4. Claim 1 is objected to because of the following informalities: In line 6, “streptavidin” is misspelled “streptabiotin”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: First paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “a uniform shape and size determined by photolithography” is added to new Claim 23 from which Claim 24 depends. While the specification teaches photolithography steps for making the microarray, the specification does not teach or describe determination of size and/or shape using photolithography. Hence, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

35 U.S.C. 112: Second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 22 are indefinite in Claim 1 because the claim is drawn to a biomolecule microarray comprising spots having a layer of biotin and a layer of avidin or streptavidin bound to the biotin. The claims are drawn to a product by process, but the process steps do not recite or define avidin or streptavidin layers or attachment.

b. Claims 1 and 22 are indefinite in Claim 1, lines 7-8 for the recitation "by means of photolithography" because it is unclear whether the recitation modifies the preceding "covering" or the following "attaching".

c. Claims 1 and 2 are indefinite in Claim 1, line 9, for the recitation "the exposed surface" because the recitation lacks proper antecedent basis in the claim.

d. Claims 23-24 are indefinite in Claim 23 because the claim is drawn to a biomolecule microarray comprising spots having a layer of biotin and a layer of avidin or streptavidin bound to the biotin. The claims are drawn to a product by process, but the process steps do not recite or define avidin or streptavidin layers or attachment.

e. Claims 23 and 24 are indefinite in Claim 23, lines 7-8 for the recitation "by means of photolithography" because it is unclear whether the recitation modifies the preceding "covering" or the following "attaching".

f. Claims 23 and 24 are indefinite in Claim 23, line 9, for the recitation "the exposed surface" because the recitation lacks proper antecedent basis in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The claims are drawn to a microarray support comprising a plurality of probe-attachable spots arrayed in a regular arrangement on the surface of the support characterized in that the spots have a layer of biotin and a layer of avidin or streptavidin on the layer of biotin. The claims further recite the process for making the microarray support. However, the courts have stated that a produce is not defined by the process of making it, but is distinguished over the prior art by the product itself.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Therefore, the instantly recited process steps do not define the microarray over the prior art.

Claims recite a process steps comprising 1) covering the surface of the support other than the spots with a cover coating, 2) by means of photolithography, 3) attaching biotin to the exposed surface and 4) removing the cover or 1) attaching biotin on the

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entire surface, 2) covering, 3) by means of photolithography, 4) leave the layer of biotin exposed.

The recited process steps do not define the microarray over a prior art microarray having regions (spots) of avidin layered on biotin because the courts have stated that a product is defined by the product itself and not by the process of making the product.

35 USC § 102 over Barrett et al

11. Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett et al (U.S. Patent No. 5,252,743, issued 12 October 1993).

Regarding Claim 1, Barrett et al disclose a microarray support for immobilizing probe biomolecules, the support comprising a plurality of small-sized probe biomolecule-attachable spots arrayed in a regular arrangement on the surface of the support (Column 2, lines 38-52) wherein the spots have a layer of biotin on the surface and a layer of avidin bound to the layer of biotin (Column 19, line 66-Column 20, line 30) wherein the spots have a uniform size and shape of less than or equal to 200 μm (Column 19, line 2 and Fig. 4-8).

While the claimed microarray is not limited by the recited method steps based on guidance from the courts cited above, Barrett et al teaches methods of making the microarray comprising attaching biotin on the entire surface of the support, covering and using photolithography whereby biotin areas other than the spot areas are covered with coating (i.e. caged) thereby providing spots of uniform size and shape of less than 200 μm (Column 19, line 2 and Fig. 4-8).

Regarding Claim 22, Barrett et al disclose the microarray wherein the spots range from 50 to 200 μm per side (Column 19, line 2 and Fig. 4-8).

Response to Arguments

12. Applicant argues that the microarray of Barrett must be stored with care because the biotin derivative on the surface can be activated if exposed to light and their microarray cannot be used with probes immobilized using UV light because the UV light would remove biotin protecting groups. Applicant asserts that in contrast to the microarray of Barrett, the instantly claimed microarray does not need “the greatest care for storage” and can be used for UV immobilization of probes. The arguments have been considered but are not found persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., does not need great care in storage and can be used for UV probe immobilization) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the arguments address uses and functions of the microarrays but do not address structural elements which distinguish the claimed microarray over that of Barrett.

Applicant further argues that Barrett does not teach “the surface of the areas other than the spot areas is left exposed or covered with a cover coating”. The argument has been considered but is not found persuasive because the non-spot areas of Barrett are covered i.e. caged resulting in a microarray comprising spots having a layer of biotin formed on the surface and a layer of avidin bound to the layer of biotin as claimed.

13. Claims 1 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Blawas et al (Langmuir, 19998, 14: 4243-4250).

Regarding Claim 1, Blawas et al disclose a microarray support for immobilizing probe biomolecules, the support comprising a plurality of small-sized probe biomolecule-attachable spots arrayed in a regular arrangement on the surface of the support (Abstract and page 4245, left column and paragraph spanning pages 4246-4247) wherein the spots have a layer of biotin on the surface and a layer of avidin bound to the layer of biotin (Abstract) wherein the spots have a uniform size and shape of less than or equal to 200 μm (page 4246 and Fig. 3).

While the claimed microarray is not limited by the recited method steps based on guidance from the courts cited above, Barrett et al teaches methods of making the microarray comprising attaching biotin on the entire surface of the support, covering and using photolithography whereby biotin areas other than the spot areas are covered with coating (i.e. caged) thereby providing spots of uniform size and shape of less than 200 μm (Abstract and page 4244, Fig. 1).

Regarding Claim 22, Blawas et al disclose the microarray wherein the spots range from 50 to 200 μm per side (page 4246 and Fig. 3).

Regarding Claim 23, Blawas et al disclose a microarray support for immobilizing probe biomolecules, the support comprising a plurality of small-sized probe biomolecule-attachable spots arrayed in a regular arrangement on the surface of the support (Abstract and page 4245, left column and paragraph spanning pages 4246-4247) wherein the spots have a layer of biotin on the surface and a layer of avidin bound to the layer of biotin (Abstract) wherein the spots have a uniform size and shape of less than or equal to 200 μm (page 4246 and Fig. 3) and have the same amount of protein probes attached to the spots being equal to or greater than 3×10^9 on each spot and wherein each probe is labeled with biotin (abstract and page 4246, Table 1).

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While the claimed microarray is not limited by the recited method steps based on guidance from the courts cited above, Barrett et al teaches methods of making the microarray comprising attaching biotin on the entire surface of the support, covering and using photolithography whereby biotin areas other than the spot areas are covered with coating (i.e. caged) thereby providing spots of uniform size and shape of less than 200 μm (Abstract and page 4244, Fig. 1).

Regarding Claim 22, Blawas et al disclose the microarray wherein the spots range from 50 to 200 μm per side (page 4246 and Fig. 3).

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic

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Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
July 7, 2004